IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

WARDELL FLEMING, *Plaintiff,* vs. JANSSEN PHARMACEUTICALS, INC. ET. AL., *Defendants.*	))))))))))	Case No. 2:15-CV-02799-JPM

PLAINTIFF'S OPPOSITION TO DEFENDANT MITSUBISHI TANABE PHARMA CORPORATION'S MOTION TO DISMISS

Defendant Mitsubishi Tanabe Pharma Corporation moves for dismissal, largely on the same grounds as Defendants Janssen Pharmaceuticals, and Johnson & Johnson. Here, Mitsubishi argues (1) this Court lacks personal jurisdiction; (2) Plaintiff's claims are preempted by federal law; (3) Plaintiff's damages are not recoverable under the Tennessee Consumer Protection ACT (TCPA); and (4) the Complaint fails to state a claim under the Federal Rules of Civil Procedure. In making these arguments, Mitsubishi ignores key allegations in the Complaint which establish a prima facie showing of personal jurisdiction under Tennessee's long-arm statute, and a plausible basis for each Count asserted; and Mitsubishi, prematurely, asks this Court to drastically broaden Supreme Court preemption precedent, a fact intense analysis, before any discovery occurs.

Nevertheless, Mitsubishi's arguments are without merit. First, the Complaint alleges sufficient jurisdictional allegations. Specifically, Mitsubishi designed and developed Invokana in collaboration with Johnson & Johnson, (*Compl.* at ¶ 18), Mitsubishi also participated in the manufacturing, marketing, distribution and sale of Invokana. (*id.* at ¶ 10), that as a result of

Mitsubishi's conduct, Plaintiff ingested Invokana and was injured, (*id.* at ¶ 40), and that Mitsubishi's tortious conduct was directed at, or occurred in Tennessee, and resulted in personal and economic injury in Tennessee. *Id.* at ¶¶ 10, 18, 40, 52.

Second, with respect to its preemption argument, Mitsubishi raises factual issues outside of the Complaint; disputed questions of fact that are premature and inappropriate for a motion to dismiss. For example, Mitsubishi would have the Court believe that even though it played a key role in the development and eventual FDA approval of Invokana, its co-Defendant submitted the NDA, and therefore Mitsubishi has no liability for the defective nature of the drugs. The truth is that Mitsubishi played an active role in Invokana's FDA approval process, and the FDA even refers to Mitsubishi as the "sponsor's partner." *FDA Medical Review of Invokana* at 29-30, *available at* http://www.accessdata.fda.gov/drugsarfda_docs/nda/2013/204042Orig1s000MedR.pdf (Feb. 8, 2013).

Third, Plaintiff has adequately pled damages which are recoverable under the TCPA.

Finally, Mitsubishi relies entirely on Defendants Janssen Pharmaceuticals and Johnson & Johnson's arguments to assert that the Complaint fails to state a claim for relief under the Federal Rules of Civil Procedure. For the reasons explained in Plaintiff's opposition to Janssen and Johnson & Johnson's motion to dismiss, Mitsubishi's *Iqbal/Twombly* arguments are without merit.

ARGUMENT

A. This Court Has Personal Jurisdiction Over Defendant Mitsubishi.

1. Applicable Law

Mitsubishi's conduct with its collaboration partners in the research, development, design, and FDA approval of Invokana for sale in Tennessee, which ultimately reached consumers in Tennessee, and injured Plaintiff in Tennessee subjects it to specific jurisdiction in Tennessee.

Specific jurisdiction arises out of or relates to a defendant's contacts with the forum. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984). "The inquiry whether a forum State may assert specific jurisdiction over a nonresident defendant focuses on the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) (internal quotations omitted). As this Court is sitting in diversity, the exercise of personal jurisdiction is defined by Tennesse's long-arm statute. *See Payne v. Motorists' Mut. Ins. Companies*, 4 F.3d 452,455 (6th Cir. 1993).[1] "The jurisdictional limits of Tennessee Law and federal constitutional due process are identical." *Id.*

The Due Process Clause bases the exercise of personal jurisdiction on whether the defendant has "minimum contacts" with the forum state "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). A state has a "manifest interest" in providing its residents with a convenient forum for "redressing injuries inflicted by out-of-state actors," particularly where the defendant "purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 473 & 475 (1985). In accordance with well-established precedent, deliberately placing products into the stream of commerce with knowledge and intent that they be sold in the forum constitutes purposeful availment. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 298 (1980).

To defeat a motion to dismiss for lack of personal jurisdiction, "plaintiffs need only make a prima facie showing of jurisdiction." *Beydoun v. Wataniya Restaurants Holding, Q.S.C.*, 768 F.3d 499, 504 (6th Cir. 2014). Further, the court "will construe the facts in the light most

[1] Plaintiff does not claim that Mitsubishi is subject to general jurisdiction in Tennessee, but instead asserts specific jurisdiction.

favorable to the nonmoving party." *Id.* The Sixth Circuit has established a three-prong specific jurisdiction analysis test: (1) "the defendant must purposely avail himself to the privilege of acting in the forum state or causing consequence in the forum state" ; (2) "the cause of action must arise from the defendant's activities there" ; and (3) "the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum to make the exercise of jurisdiction over the defendant reasonable." *Devault-Graves Agency, LLC v. Salinger*, 2015 WL 6143513, at *4 (W.D. Tenn. Oct. 19, 2015) (citing *Southern Machine Co. v. Mohasco Indus., Inc.*, 401 F.2d 374, 381 (6th Cir. 1968). Courts will look to the contacts that the defendant's create with the forum State, not just citizens who reside in the State. *Walden v. Fiore*, 134 S.Ct. 1115, 1122 (2014). Courts have found personal jurisdiction over defendants where the defendants purposefully entered into a contractual relationship that "envisioned continuing and wide-reaching contacts" in the forum state. See e.g. *id.* (citing *Burger King*, 471 U.S. at 479-80.

2. This Court may exercise personal jurisdiction over Defendant Mitsubishi under Tennesse's long-arm statute and Federal Due Process.

Plaintiff alleges that Mitsubishi designed and developed Invokana in collaboration with its partners, Johnson & Johnson. *Compl.* at ¶ 18. Then Johnson & Johnson's wholly owned subsidiary, Janssen, acquired the rights to market and sell Invokana to patients in Tennessee and other U.S. markets. *Id.* at ¶ 19. Mitsubishi, whether directly or through its agents, collectively researched, developed, designed, licensed, manufactured, marketed, distributed, and sold Invokana in Tennessee, with a reasonable expectation that Invokana would be used in Tennessee. *Id.* at ¶¶ 13-15. Mitsubishi, directly or through its agents, conducted nationwide sales and marketing campaigns, including in Tennesse, to promote Invokana. *Id.* at ¶ 34. Mitsubishi also disseminated false and misleading information about Invokana to health care professionals in

Tennessee with the expectation that such information be used and relied on in Tennesse. *Id.* at ¶ 13. As a result of these acts, Plaintiff was prescribed Invokana in Tennessee, ingested Invokana in Tennessee, and suffered severe injury in Tennessee. *Id.* at ¶¶ 15, 35-36, 40, 45.

The Complaint does refer to the defendants collectively, but it also provides a factual predicate which explains, to the extent known or knowable by Plaintiff, each Defendant's identity, and the role each Defendant played in the design, development, research, testing, manufacturing, marketing and sale of Invokana. *See id.* at ¶¶ 7-49. Mitsubishi argues that collectively referring to the defendants as "Defendants" renders the Complaint defective because it provides no factual basis to distinguish each Defendants' conduct. *Mitsubishi Def. Mem.* at 7. Aside from the factual predicate established in the Complaint, Mitsubishi also fails to acknowledge that the allegations are specific, and they are alleged against all Defendants, because to the extent it is known or knowable to Plaintiff, all Defendants engaged in the same or substantially similar activity, acted in concert, or as agents to each other with regards to Invokana.

Here, the Complaint articulates the factual basis for Mitsubishi's liability because it alleges that Mitsubishi researched, developed, designed, licensed, manufactured, distributed, supplied, marketed and sold Invokana to Plaintiff in Tennessee. *Compl.* at ¶¶ 10, 18, 54. The precise details of the interrelated conduct of each Defendant are not known and not knowable to Plaintiff without discovery. Nevertheless, under the applicable pleading standard, the Complaint alleges sufficient jurisdictional facts to demonstrate a prima facia showing of personal jurisdiction. Furthermore, under the Sixth Circuit's three-prong test, the Complaint alleges sufficient contacts with the forum and sufficient availment by Mitsubishi. Plaintiff alleges Mitsubishi transacted and solicited a significant amount of business in Tennessee through its

agents and representatives, and derived a substantial amount of revenue from Tennessee. *Id.* at ¶ 12. The total sales of Invokana were so robust that the drug reported $278 million in earnings from just in the first quarter of 2015, which necessarily includes significant sales in Tennessee. *Id.* at ¶ 20. If sales continue apace, Invokana will have earned over ***$1 billion*** on just Invokana in 2015- and it has only been on the U.S. market since April of 2013.[2]

These allegations do not make it "impossible to tell from the face of the complaint which defendants were accused of which violations, what specific acts constituted violations, or when alleged violations occurred[.]" *Rotello v. Clayton Homes of Delaware, Inc.*, No. 3:03-CV-573, 2006 WL 2771018, at *4 (E.D. Tenn. Sept. 25, 2006). Thus the instant Complaint is remarkably different than Defendant's cited authority, *Rotello* and *Jacox v. City of Memphis*, No. 12-2337-JDT/DKV, 2013 WL 4648303 (W.D.Tenn. Aug. 29, 2013), where the plaintiffs made no effort to attribute specific acts to specific defendants. *See Rotello*, 2006 WL 2771018, at *4; *Jacox*, 2013 WL 4648303, at *4. Defendant's remaining authority, though also a case involving Invokana, suffers the same problem as *Rotello* and *Jacox*. *See Defs. Mem.* at 7, Ex. B, *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM (N.D. Ga. Mar. 24, 2016). Moreover, *Brazil* is a case about a different plaintiff, filed in a different jurisdiction, subject to different law, argued by different counsel, and carries little weight here.

In summary, Plaintiff alleges that Mitsubishi designed Invokana, Mitsubishi, along with its partners, placed Invokana in the stream of commerce, marketed Invokana in Tennessee, sold Invokana in Tennessee, derived substantial revenue from sales of Invokana in Tennessee, and injured Plaintiff in Tennessee. Accordingly, Plaintiff has alleged substantial factual content, not

[2] Invokana sales are likely to far exceed this number, as Johnson & Johnson earned ***$890 million*** on U.S. sales of Invokana in the first 9 months of 2015. *See* Johnson & Johnson Third Quarter 2015 Sales of Key Prods. at 2, *available at* http://files.shareholder.com/downloads/JNJ/1188176531x0x854183/3152FFAB-82A7-4F38-AA75-D25F107767DB/Sales_of_Key_Products_Franchises_3Q2015.pdf.

just mere conclusory allegations, establishing that this Court may exercise personal jurisdiction over Defendant Mitsubishi. There can be no question of the Court's jurisdiction. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 759 n.13 (2014) ("corporation can purposefully avail itself of a forum by directing its agents or distributors to take action there"); *Asahi Metal Indus. v. Superior Court of Cal.*, 480 U.S. 102, 112 (1987) ("designing the product for the market in the forum State" or "marketing [a] product through a distributor" each can constitute purposeful availment).[3]

B. Plaintiff's Design Defect Claims Are Not Preempted.

Next, Defendant tries to shoehorn this case, which involves a brand-name drug, into the Supreme Court generic drug preemption decisions, *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2367 (2011) and *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013), arguing that all design defect claims are preempted as a matter of law under two distinct legal theories. First, Mitsubishi claims it is entitled to design, develop, and profit from a drug, yet avoid liability for the damaged caused simply because it entered into a licensing agreement with Janssen. Second, Mitsubishi asks the Court to broaden the holding in *Bartlett* to encompass brand-name drug manufacturers, so that it cannot be held liable for damages caused by defects in its products even if they know a drug is unreasonably dangerous. Thus, Defendant seeks to reap the profits from its enterprise, immune from liability. Even if the Court wished to entertain these faulty legal theories, they implicate fact-specific issues that cannot be addressed prior to discovery. Mitsubishi's preemption arguments are both premature and without merit.

1. Entering into a licensing agreement does not grant immunity from suit.

Mitsubishi "is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate

[3] In the alternative, to the extent the Court finds Plaintiff's allegations insufficient, Plaintiff requests the opportunity to take discovery to further develop jurisdictional facts. *See infra* Section E.

commerce, either directly or indirectly through third parties or related entities, . . . the prescription drug Invokana." *Compl.* at ¶ 10. After designing and developing Invokana, Mitsubishi entered into a licensing agreement with Janssen, whereby its co-Defendant acquired the rights to market and distribute Invokana. *Id.* at ¶ 19. Mitsubishi claims that Janssen holds the NDA for Invokana. Based on this, Mitsubishi suggests it is like a generic drug manufacturer, unable to change the design or labeling of Invokana, and immune from liability. Thus, Mitsubishi's argument is based on the identity of Invokana's NDA holder, a factual issue outside of the Complaint. Pursuant to Rule 12(d), the Court should either exclude this extraneous material, or convert Defendant's motion to one for summary judgment, first giving Plaintiff ample notice and time to conduct the necessary discovery. However, even if the Court takes judicial notice of Mitsubishi's factual assertion, the Court must construe all facts "in the light most favorable to the [Plaintiff]." *Papasab v. Allain*, 478 U.S. 265, 283 (1986).

In inserting this factual issue, Mitsubishi conveniently neglects to mention that it actively participated in the FDA approval process. The FDA's medical review identifies Mitsubishi as "the sponsor's partner," and explains that it received and relied on Mitsubishi's research and clinical trials during the approval process. *See FDA Medical Review of Invokana* at 29-30, *available at* www.accessdata.fda.gov/drugsarfda_docs/nda/2013/204042Oril1s000MedR.pdf (Feb. 8, 2013).[4] As this motion was filed before Plaintiff received any discovery, Plaintiff lacks access to the evidence necessary to determine the full extent of Mitsubishi's involvement in the approval process. Nor can Plaintiff access information on Mitsubishi's influence over other pivotal issues affecting the design, labeling, marketing, and promotion of Invokana. However, it

[4] Plaintiff introduces this information merely to illustrate the evidentiary weight of the pleadings. These facts can be considered by the Court without triggering a Rule 56 conversion. *See e.g. Geinosky v. City of Chicago*, 675 F.3d 745, n.1 (7th Cir. 2012) (explaining that a plaintiff has much more flexibility when opposing a Rule 12(b)(6) motion, provided that any elaboration on the factual allegations in the pleadings are consistent with the pleadings).

is clear that Mitsubishi is not the powerless bystander it claims to be. Construing all facts in the light most favorable to Plaintiff, Mitsubishi certainly cannot show preemption should apply.

The recent case *In re Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299, 2014 WL 4286927 (W.D. La. Aug. 28, 2014) examined many of these same issues, albeit with the benefit of a fully developed record. In *Actos*, plaintiffs filed suit against Takeda and Eli Lilly for damages caused by a brand name drug. The defendants had a co-promotion agreement regarding the sale of Actos in the U.S., but Takeda held the NDA. *Id* at *1-2. The jury ultimately entered a verdict against both defendants. *Id.* at *20-23. Eli Lilly sought post-judgment relief under the preemption doctrine, arguing it should be treated like a generic drug manufacturer. *Id.* at *1, 17-23. The court examined the factual record, noting that Eli Lilly participated in formulating the drugs label and marketing materials. *Id.* at *9, 11-13, 19.[5] Therefore, the rationale underlying preemption of claims against generic drug manufacturers was not applicable. *Id*. at *17. Eli Lilly had the ability to affect the drug's warnings and the duty to provide an adequate warning, so preemption did not apply. *Id.* at *19.

Here, Defendant relies on *In re Darvocet, Darvon & Propoxyphene products Liability Litigation*, 756 F.3d 917 (6th Cir. 2014), which involved claims brought against a former brand name drug manufacturer that sold its NDA after a drug went generic. *Id.* at 923-24. The plaintiff filed suit eight years later, claiming the defendant continued to manufacture a generic form of the drug. *Id.* at 940. Because the defendant had completely divested itself of its rights over the brand drug and had no power over the drug's warnings, the court found plaintiff's warning-based claims were preempted. *Id.* However, *In re Darvocet* is distinguishable in two key respects: Invokana is not generic a drug, and Mitsubishi has not sold all of its rights to the drug.

[5] This was particularly pertinent because "virtually every document used in marketing or distribution is considered 'labeling' under" FDA regulations. *Id.* at *17 (quoting 21 C.F.R. § 202(i)(2)).

Mitsubishi's remaining authority, all of which involve claims against the distributor, are equally distinguishable. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. 11) MDL No. 2243, 2012 WL 181411 (D.N.J. Jan. 17, 2012); Stevens v. Cmty. Health Care, Inc., No. ESCV200702080, 2011 WL 6379298 (Mass. Super. Ct. Oct. 5, 2011).* Mitsubishi is no middleman distributor. Nor is it a powerless generic drug manufacturer. Mitsubishi designed and developed Invokana, provided support for the drug's FDA approval, granted the distribution rights to its co-promoters, and generated revenue from the drug. As with the co-promoters in *Actos*, there is no basis for preemption.

Because this motion was filed before discovery has occurred, Plaintiff is in the position of making legal arguments in the abstract, based only on publicly available information. Without discovery, Plaintiff cannot know the precise powers or rights Mitsubishi retained under the licensing agreement, its role in the labeling, design, promotion, and sale of Invokana, or the extent of its participation in the FDA approval process. These facts are highly relevant to the Court's analysis. *See In Re Actos*, 2014 WL 4286927, at *9, 11-13, 19 (analyzing co-promotion agreement, marketing activities, involvement in warning-related decisions, and communications with the FDA as part of the preemption analysis). Therefore, Mitsubishi's preemption arguments are premature.

As we remain at the motion to dismiss stage, Plaintiff lacks the factual record necessary to fully formulate his argument. But here, like *Actos*, multiple pharmaceutical manufacturers have entered into an agreement regarding the marketing and distribution of brand name drugs that caused significant harm. And, like *Actos*, there is no "sameness" requirement preventing Mitsubishi (or any other Defendant) from ensuring that Invokana is not inherently defective or that Invokana's labeling, marketing documents, and other materials adequately warn of the risks.

Viewing all factual allegations in the light most favorable to Plaintiff and drawing all reasonable inferences in his favor, there is no basis for preemption.[6]

2. Plaintiff's design defect claims are not preempted.

Mitsubishi's next argument mirrors that of its co-Defendants, seeking to expand the Supreme Court generic drug preemption decision, *Mutual Pharmaceutical Company v. Bartlett*, 133 S.Ct. 2466 (2013), to preempt all pharmaceutical design defect claims. In essence, Defendants argue they should be able to develop, market, and sell a drug — even if they know it is unreasonably dangerous — until the FDA affirmatively steps in to stop them, and even then they should bear no financial responsibility for the damage caused. Thus, Defendants posit that the FDA should serve as *de facto* judge and jury, leaving Courts without power and consumers without remedy. Such a premise should be rejected out of hand.

The Supreme Court's preemption rulings evidence a distinct dichotomy in how the Court views claims against the generic and brand name drug manufacturers. With respect to failure to warn claims, the Court held that claims against brand name drug manufacturers are not preempted by federal law, whereas most claims against generic manufacturers are impliedly preempted. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (brand name); *Mensing*, 131 S.Ct at 2578 (generic). In *Bartlett*, the Court ruled that certain generic design defect claims are preempted. 133 S.Ct. at 2479. The Supreme Court has never held that federal law preempts claims against a brand name drug manufacturer. In fact, the deciding factor in both *Mensing* and *Bartlett* ultimately turned on a generic drug manufacturer's inability to change a drug's label. *Id.* at 2478-79.

[6] In the alternative, Plaintiff requests the opportunity to take discovery to further develop these facts. *See infra* Section E

As explained in Plaintiff's response to Jansenn and Johnson & Johnson's motion to dismiss, and the many cases cited therein, the preemption findings in *Mensing* and *Barlett* rely on the duty of "sameness" imposed only on generic drug manufacturers, and therefore are not applicable to brand-name drugs. *Mensing*, 131 S.Ct. at 2576-78; *Bartlett*, 133 S.Ct. at 2476-77; Doc. 18 at 6-10. Mitsubishi attempts to discount this authority by referring to cases that have cited *Mensing*, claiming this proves *Mensing* should be applied outside of the generic drug context. However, the first two cases cite *Mensing* for a generic legal premise. *Wos v. E.M.A.*, 133 S.Ct. 1391, 1398 (2013); *Horseman's Benevolent & Protective Assoc. v. Dewine*, 666 F.3d 997, 1000 (6th Cir. 2012). And the third examined the factually unique situation of a failure to warn claim in which the Changes Being Effected process was unavailable to a brand name drug manufacturer. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 41-43 (1st Cir. 2015). None of these cases would support expanding *Mensing* to preempt design defect claims against brand-name drug manufacturers. In fact, the plain language of *Mensing* actually forecloses such a possibility:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name Drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.

Mensing, 131 S.Ct. at 2582.

Despite this clear limiting language, Mitsubishi suggests the Court should focus on two isolated clauses from *Bartlett* and *Mensing* (*Bartlett*, 133 S.Ct. at 2471: "whether generic or brand-name" ; *Mensing*, 131 S.Ct. at 2581: "without the Federal Government's special permission and assistance"), and combine them to create an entirely new category of impossibility preemption affecting brand-name design defect claims. *See Def.'s Mem.* at 16.

The recent medical device case, *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2015 WL 7761033 (S.D.W. Va. Dec. 2, 2015) rejected this argument, finding *Bartlett* declined to apply the impossibility preemption standard proposed by Defendants. *Id.* at *5-6

> The defendants' focus demonstrates their misunderstanding of the nature of the impossibility found in *Mensing*, which was the direct conflict between the "state law duty to change the label and the[ ] federal law duty to keep the label the same." In *Mensing*, there was no official regulatory process by which a generic could change its label, so the generic manufacturer was "barred" from taking the action state law required. This is completely different from the defendants' situation in the instant case. Unlike the law imposing the duty of sameness for generics, there is no federal law prohibiting design changes to medical devices, particularly changes representing advances in safety.

Id. at *6.

Trahan v. Sandoz, Inc., No. 3:13-cv-350-J-34MCR, 2015 WL 2365502 (M.D. Fla. Mar. 26, 2015), also rejected Mitsubishi's argument, cautioning against reliance on *Bartlett's* "generic or brand name" clause in isolation. Instead, the clause must be examined in context, taking into account existing Supreme Court precedent. *Id.* at *6, n.5. *Bartlett* explicitly recognized that "federal law establishes no safe-harbor for drug companies." 133 S.Ct. at 2479. And the *Wyeth* Court found that Congress did not intend for FDA oversight to preempt state tort law. 555 U.S. at 574-75. In fact, the Court recognized the vital importance of state tort suits, which incentivize the prompt disclosure of drug safety risks, and compensate injured parties. *Id.* at 579. In this context and on this basis, *Trahan* held:

> this Court does not interpret the *Bartlett* decision to change course and foreclose all design defect claims against prescription drug manufacturers in the absence of an express statement that it was doing so. To the contrary, because the *Bartlett* Court stated its express understanding that it was not providing a safe-harbor for drug companies, the Court declines to interpret *Bartlett* in such a way as to preempt [plaintiff's] claims . . . .

2015 WL 2365502, at *6, n.5.

Federal law does not prohibit brand-name drug manufacturers from designing a reasonably safe drug before FDA approval, nor does it prohibit them from changing a drug's design post-approval to ensure it is reasonably safe. Mitsubishi tries to avoid Plaintiff's pre-

approval design defect claim by relying on *Yates v. Ortho-Mcneil-Janssen Pharms., Inc.*, 808 F.3d 281 (6th Cir. 2015). As previously explained in Plaintiff's response to Johnson & Johnson and Janssen's motion to dismiss, Defendants ignore that in *Yates*, a case decided at the summary judgment stage, the Sixth Circuit continued to recognize "no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs," and was not persuaded that it is always impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval. *Id.* at 300 (quoting *Wimbush v. Wyeth*, 619 F.3d 632, 643 (6th Cir. 2010)).

Notwithstanding Mitsubishi's arguments, the "sameness" requirement that led to preemption in *Mensing* and *Bartlett* does not apply to brand name drug manufacturers. Therefore, claims against brand name drug manufacturers are not preempted. *See Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014) (*Bartlett* preemption does not extend to brand name drugs); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2436, 2015 WL 7075916, at *21-24 (E.D. Pa. Nov. 13, 2015) (holding same); *Trahan*, 2015 WL 2365502, at *6 (preemption does not affect duty to design reasonably safe product prior to FDA approval). *See also Ansagay v. Dow Agrosciences LLC*, No. 15-184, 2015 WL 9582710, at *10 (D. Haw. Dec. 29, 2015) ("Unsurprisingly, courts construing *Bartlett* and *Mensing* have pointed out that preemption in both cases depended on the defendants' status as generic drug manufacturers.").

3. Mitsubishi's preemption arguments are premature.

Defendant's preemption arguments are fact-based and inappropriate at the motion to dismiss stage. As set forth above, Mitsubishi's failure to warn preemption argument implicates

the terms of the Defendant's licensing agreement, the rights and responsibilities Mitsubishi retained over Invokana, the extent of Mitsubishi's participation in the approval and labeling of Invokana, and its involvement in the marketing and promotion of the drug. None of these facts are currently available or before the Court. Defendant's design defect preemption argument also implicates important factual questions. The argument's foundation, faulty as it may be, rests on the presumption that Plaintiff's claims implicates a "major change" under FDA regulations, triggering the need for FDA approval. *See* 21 C.F. R. § 31.70(b)(2)(i). This has yet to be determined. As such, Mitsubishi's preemption arguments are premature, rest on a faulty interpretation of the law, and are wholly without merit.

Mitsubishi points to two recent cases for support. *Batoh v. McNeil-PPC, Inc.*, No. 3:14-cv-01462 (MPS), 2016 WL 922779 (D. Conn. Mar. 10, 2016); *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028 (N.D. Ala. Mar. 21, 2016). However, Defendant's cited authority provides little support for its arguments, and they illustrate that Mitsubishi's preemption arguments are premature, as *Batoh* was decided at the summary judgment stage, after the parties were given the opportunity to conduct discovery. *See Batoh*, 2016 WL 922779, at *1 Moreover, the facts of *Batoh* and *Barcal* are not analogous to the instant case, as *Batoh* is a case about Motrin, which was on the market for decades before it caused the plaintiff's injuries, and *Barcal* is a case about a fertility drug that was on the market for decades before it caused the plaintiff's injuries, and it was approximately 20 more years after the injury that the plaintiff filed suit. *See Batoh*, 2016 WL 922779, at *1; *Barcal*, 2016 WL 1086028, at *1-2.

These cases are vastly different to the facts presented here, where Plaintiff began using Invokana shortly after each drug was introduced to the market, and his injuries manifested quickly thereafter, leading to this suit. Even *Yates* recognized the importance of the length of

time the drug is on the market, in comparison to the time of injury, and the time of filing suit. *See Yates*, 808 F.3d at 300 (distinguishing the facts of *Wimbush*, where the drug was on the market for just over a year, with the *Yates* facts, where Ortho-Evra was on the market for four years before the plaintiff even used the product, and was still on the market at the time of the *Yates* decision in 2015). Here, Plaintiff's design defect theory of liability rests on Defendants' duty to design and develop a reasonably safe product prior to FDA approval- a duty which is clearly not preempted. Moreover, Defendants' duty, as articulated by the Complaint, would not require Defendants to exit the market, because there are numerous alternative, and effective type 2 diabetes medications with much safer safety profiles than Invokana. *Compl.* at ¶ 54(g). Thus, the decisions reached in *Yates*, *Barcal* and *Batoh* do not apply to this case.

C. Plaintiff's Damages are Recoverable Under the TCPA.

To recover under the TCPA, the plaintiff must allege and eventually prove that the defendant engaged in an unfair act or practice declared unlawful by the TCPA, and that the defendants' conduct caused an "ascertainable loss of money or property, real, personal, or mixed, or any article, commodity, or thing of value wherever situated . . . ." *Tucker v. Sierra*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005) (citing Tenn. Code Ann. § 47-18-109(a)(1). "[T]he TCPA is explicitly remedial, and Tennessee courts are therefore required to construe it liberally to protect consumers in Tennessee and elsewhere." *Id.*

Here, Plaintiff alleges that Defendants violated the TCPA, that he suffered damages as a result of Defendants' violation(s), and Plaintiff requested that this Court award economic damages. *Compl.* ¶¶ 224-227, prayer for relief. As the end purchaser of Invokana, Plaintiff's economic damages stem from the purchase price of the drug that he would not have purchased but for Defendants' wrongful conduct. *Id.* at ¶ 89, 200. Plaintiff's economic damages are separate and distinct from Plaintiff's damages which flow from the personal injury he suffered

Thus, Plaintiff has pled damages which are recoverable under the TCPA. *See Riddle v. Lowe's Home Centers*, 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011).

D. The Complaint Pleads Plausible Claims For Relief Sufficient To Satisfy Rule 8, and Where Applicable, Rule 9.

Mitsubishi relies on its co-Defendants' arguments to claim that the Complaint does not satisfy Rule 8 and where applicable, Rule 9, and a recent Eastern District of Louisiana case. As plaintiff has previously explained, Defendant's arguments regarding the pleading standard are without merit. Doc. 18 at 11-16. Therefore, Plaintiff hereby incorporates his response to Mitsubishi's co-Defendants here.

As additional support, here, again, Mitsubishi relies on a district court case which was decided under different law, regarding a different complaint, a different plaintiff, and argued by different counsel. *Guidry v. Janssen Pharms., Inc.*, No. 15-4591, 2016 WL 633673 (E.D. La. Feb. 17, 2016). Defendant's reliance on *Guidry* is misplaced. There, the Court found that the Complaint "fail[ed] to plead or support how Invokana's design is defective, in what way Invokana could have remedied the defect, or how the alleged defect caused her particular injuries." *Id.* at *4. Here, the same is not true. The instant Complaint explains that Invokana forces excess and unmetabolized sugar through the kidneys of a population already at risk of kidney disease, (*Compl.* at ¶ 24), that alternative, safer formulations for diabetes treatment were available, (*id.* at ¶ 54(g)), and that Plaintiff would not have taken Invokana had he been warned of the risks. *Id.* at 45.

As *Guidry* acknowledges, Invokana's prescribing information mentions "renal-related" adverse effects. *Guidry*, 2016 WL 633673, at *4, n. 9. However, as Plaintiff has alleged, Invokana does not warn of kidney failure, the injury suffered by Plaintiff. *Compl.* at ¶ 86. Defendants may ask this Court to take judicial notice of Invokana's prescribing information,

nevertheless, the prescribing information in effect at the time Plaintiff ingested Invokana, and the adequacy of the warnings issued in the prescribing information are factual questions that are premature at this stage, with Plaintiff having no benefit of discovery. *See In re Aredia and Zometa Products Liability Litigation*, No. 3:06-MD-1760, 2009 WL 8638121, at *1 ("Whether the warnings were adequate to warn a physician of the possibility that the drug might be causing the condition experienced must be presented through the testimony of an expert."). Thus, at the motion to dismiss stage, this Court, viewing all factual allegations in the light most favorable to Plaintiff and drawing all reasonable inferences in his favor, should find that the Complaint's allegations have been adequately pled.

E. Request for Discovery

To the extent the Court chooses to entertain Mitsubishi's jurisdiction or preemption arguments, Plaintiff respectfully requests leave to conduct discovery. Mitsubishi posits that its status as a foreign corporation serves to particularly insulate it from jurisdictional discovery. However, Plaintiff has alleged substantial jurisdictional facts which, at the very least, entitle Plaintiff to limited discovery on that issue. Here, the Court may proceed in three ways: (1) decide the motion on the pleadings; (2) "permit discovery in aid of deciding the motion" ; or (3) "conduct an evidentiary hearing to resolve any apparent factual questions." *See Noval Intern. Resources, LLC v. Andec, Inc.* 875 F. Supp.2d 804, 806-07 (W.D. Tenn. Jun. 21, 2012) ("Dismissal is proper only if [the plaintiff's]alleged facts collectively fail to state a prima facie case for jurisdiction." (quoting *Carrier Corp. v. Outokumpu Oyj*, 673 F.3d 430, 449 (6th Cir. 2012)).

As set forth above, Plaintiff sufficiently establishes personal jurisdiction over Mitsubishi. Should the Court disagree, Plaintiff's allegations coupled with Invokana's astronomical sales figures make a colorable showing that the Court may exercise personal jurisdiction over

Mitsubishi. This is more than sufficient to justify jurisdictional discovery. If permitted to conduct discovery for jurisdictional and preemption purposes, Plaintiff would seek, at a minimum, Corporate Representative depositions pursuant to Federal Rule of Civil Procedure 30(b)(6) and related document requests on the following: (1) Mitsubishi's corporate structure; (2) its involvement in the development, manufacturing, approval, labeling, sale and promotion of Invokana; (3) the sale, distribution, and marketing of Invokana in Tennessee; (4) contractual agreements among the Defendants; (5) studies and other clinical trials related to Invokana; (6) the design, development, and testing of Invokana; and (7) scientific studies showing increased risks of Invokana and related communications with the FDA.

F. Alternately, Plaintiff Requests the Opportunity to Amend His Complaint.

Alternately, should this Court find Plaintiff's Complaint defective in any way, Plaintiff respectfully requests leave to amend. Under Rule 15(a)(2), leave to amend should be "freely" granted when "justice so requires." Although Plaintiff firmly believes his Complaint is sufficient as is, should this Court determine otherwise, Plaintiff should be afforded the opportunity to reallege his claims in a manner acceptable to all parties and to this Court.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to dismiss.

Dated: May 20, 2016

Respectfully submitted,

/s/ *Travis P. Lepicier*
ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 20th day of May, 2016, a copy of the foregoing was filed electronically with the Clerk of Court to be served via the Court's electronic case filing system on all counsel of record.

/s/ *Travis P. Lepicier*
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